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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,755	11/15/2001	Charles A. Kunsch	PF198D1C1	7518

22195 7590 08/28/2003

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/987,755

**Applicant(s)**

KUNSCH ET AL.

**Examiner**

Anne Marie S. Wehbe

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**Election/Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to isolated polynucleotides and vectors encoding said polynucleotides, classified in classes 536 and 435, subclasses 23.1, and 320.1 respectively.
- II. Claims 4-6, drawn to genetically engineered cells, methods of producing said cells, and methods of using said cells to produce protein, classified in class 435, subclasses 325, 455, and 70.1.
- III. Claims 7-8, and 11-12, drawn to isolated polypeptides and methods of using said polypeptides to treat a patient, classified in classes 530 and 514, subclasses 350 and 2 respectively.
- IV. Claims 9, drawn antibodies, classified in classes 530, subclass 187.1 .
- V. Claims 10 and 13, drawn to a compound which inhibits a polypeptide, classified in class 514 subclass 1.
- VI. Claims 14, drawn to process of diagnosis involving detection of mutations in nucleic acid classified in class 435, subclass 6.
- VII. Claim 15, drawn to a process of diagnosis involving detection of a polypeptide, classified in class 435, subclass 7.1.
- VIII. Claims 16-17, drawn to methods of identifying compounds by contacting cells with a compound, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons.

- 1) Inventions I-IV are patentably distinct in that polypeptides, nucleic acids, antibodies, and cells expressing a protein are substantially different in structural, physical, and biological properties, are made using different reagents and methods, and can be used for substantially different purposes. In particular, note that the polypeptide can be made synthetically and does not require the nucleic acid, and that the antibody can be naturally occurring and does not require the polypeptide for its manufacture. Further, while cells transfected with a vector do utilize the nucleic acid, the transfected cells are structurally and functionally different from isolated nucleic acids and vectors. Further, the nucleic acids and vectors can be used for purposes other than making transfected cells, such as their use in in vitro hybridization assays.
- 2) Inventions I-IV are patentably distinct from inventions V in that the compound of invention V inhibits the polypeptide of invention III and therefore is functionally substantially different from the polypeptide, the nucleic acid, cells containing the nucleic acid encoding the polypeptide of inventions I-III, or an antibody which binds to the polypeptide.
- 3) Inventions I-V are patentably distinct from inventions VI-VIII in that the nucleic acids, polypeptides, and cells can be used for substantially different purposes than the in vitro testing or diagnostic methods of inventions VI-VII, such as their use for therapy in vivo.
- 4) Inventions VI-VIII are patentably distinct in that the diagnostic and screening methods of the different inventions utilize substantially different reagents which operate under substantially different chemical conditions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D.  
PRIMARY EXAMINER

